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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/563,779	07/24/2006	Richard Dale	70269USPCT	3141

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EXAMINER

ZHENG, LI

ART UNIT	PAPER NUMBER
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1638

MAIL DATE	DELIVERY MODE
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03/20/2009

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/563,779	Applicant(s) DALE ET AL.	
	Examiner LI ZHENG	Art Unit 1638	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 30 December 2008.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-18 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-18 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 06 January 2006 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

1. Claims 1-18 are pending.

Election/Restrictions

2. Applicant's election with traverse of Group I, claims 1-4, 10-14, 16-17, as well as herbicides, direct phytotoxic substance, 3-D-aspartate, amino acid change in position 213 being serine as species election and submission of new claim 18 in the reply filed on 12/30/2008 are acknowledged.

The objection to claims 5-9 and 15 are withdrawn due to claim amendment.

Applicants argue that the alleged species should not be separated out and definitely fit the unity of invention (response, page 3, 3rd paragraph). Applicants further argue that the compound in claim 2 as well as D-aspartate or D-glutamate are not species (response, page 3, 4th paragraph).

During the examination, it is found that there is no undue burden to search and examine all the species together. The species elections are withdrawn.

Claims 1-18 are examined on the merits.

The requirement is deemed proper and is therefore made FINAL.

Specification

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3. The abstract of the disclosure is objected to because the abstract should be limited within 150 words. Correction is required. See MPEP § 608.01(b).

4. The specification is objected to under 37 CFR 1.821(d) as failing to refer to a sequence by use of its sequence identifier preceded by "SEQ ID NO:". The polypeptide sequences shown on page 24, lines 23-24 should be identified by SEQ ID NOs.

Claim Objections

5. Claims 10 and 15 is objected to because "-" is missing after "D" and "L".

Claim 17 is objected to because claim 14 is not drawn to an oxidase.

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Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

6. Claims 1-18 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

In claim 1, the last step of the method in instant claims is inconsistent with the preamble. The last step only results in introduction of the vector in any plant,

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whereas the preamble states that the method is for alleviating plant pest infestation. It is suggested to add a step to select for plants with male or female sterility.

Written Description

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

7. Claims 1-18 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The claims are drawn a method of producing any male or female sterile plants using a mutant D-amino acid oxidase obtainable from *Rhodotorula gracilis* with a lysine at position 58 (emphasis added). The claims also read on using double, triple or quadruple mutant with additional mutation in position 213, 238 and/or 223.

Given the broad interpretation of “using a mutant D-amino acid oxidase obtainable from *Rhodotorula gracilis* with a lysine at position 58”, the claims encompass any D-amino acid oxidase with a lysine at position 58 and are not so

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limited to F58K mutant D-amino acid oxidase of *Rhodotorula gracilis*.

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The specification teaches several known D-amino acid oxidases from several organisms (specification, the paragraph bridging pages 7-8). The specification also teaches isolation of cDNA encoding those D-amino acid oxidases and generation of a mutant D-amino acid oxidase of *Rhodotorula gracilis* with a lysine at position 58 (F58K), double mutants of F58K,M213S and F58K,M213T) and a triple mutant of F58K,M213S,Y223H (specification, the paragraph bridging pages 23-24, and page 45, lines 4-14). The specification also teaches that wild-type *R. gracilis* D-amino acid oxidase exhibits no detectable ability to oxidize D-phosphinothricin and only low activity when D-aspartate is used as substrate. F58K mutant form exhibits some low activity versus phosphinothricin and moderate activity with D-aspartate. The double mutant F58K,M213S exhibits a very high activity versus D-aspartate and a high activity with D-phosphinothricin. Whereas the triple mutant F58K,M213S,Y223H exhibits a moderate activity versus both substrates (specification, page 45, lines 4-14). The specification also teaches that F58K,M213T mutant is 2-5x more active than the F58K,M213S mutant using D-phosphinothricin as substrate.

The Applicants do not identify essential regions of the D-amino acid oxidases, nor do Applicants describe any D-amino acid oxidase other than the ones disclosed in the paragraph bridging pages 7-8). There is no sequence alignment to indicate how to correlate the residue F58 of D-amino acid oxidase of *Rhodotorula gracilis* to the residue in other D-amino acid oxidases. Similar

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correlation problems are also found for positions 213, 238 and 223 of the D-amino acid oxidase of *Rhodotorula gracilis*.

The Federal Circuit has recently clarified the application of the written description requirement to inventions in the field of biotechnology. See University of California v. Eli Lilly and Co., 119 F.3d 1559, 1568, 43 USPQ2d 1398, 1406 (Fed. Cir. 1997). In summary, the court stated that a written description of an invention requires a precise definition, one that defines the structural features of the chemical genus that distinguishes it from other chemical structures. A definition by function does not suffice to define the genus because it is only an indication of what the gene does, rather than what it is. The court goes on to say, "A description of a genus of cDNAs may be achieved by means of a recitation of a representative number of cDNAs, defined by nucleotide sequence, falling within the scope of the genus or of a recitation of structural features common to members of the genus, which features constitute a substantial portion of the genus." *See University of California v. Eli Lilly and Co.*, 119 F.3d 1559; 43 USPQ2d 1398, 1406 (Fed. Cir. 1997).

Applicants fail to describe a representative number of any F58K mutant D-amino acid oxidases. Applicants only describe F58K mutant D-amino acid oxidases of *Rhodotorula gracilis*. Furthermore, Applicants fail to describe structural features common to members of the claimed genus of mutant D-amino acid oxidases. Hence, Applicants fail to meet either prong of the two-prong test set forth by *Eli Lilly*. Furthermore, given the lack of description of the necessary elements essential for mutant D-amino acid oxidases, it remains unclear what

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features identify claimed mutant D-amino acid oxidases. Since said genus has not been described by specific structural features, the specification fails to provide an adequate written description to support the breadth of the claims.

Conclusion

No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Li Zheng whose telephone number is 571-272-8031. The examiner can normally be reached on Monday through Friday 9:00 AM - 5:30 PM EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anne Marie Grunberg can be reached on 571-272-0975. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/Li Zheng/
Examiner, Art Unit 1638

